IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of A. K. Gunnar Aberg and George E. Wright and Jan L. Chen and Andrew T. Maioli

Application No.: 10/069,663 Filing Date: 02/27/2002

For: Optically Active Isomers of Ketotifen and Therapeutically Active Metabolites Thereof

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents P.O.Box 1450, Alexandria, VA 22313-1450
on December 14, 2006 (Date)
Kevin S. Lemack
Name of applicant, assignee, or Registered Representative
Signature
December 14, 2006
Date

DECLARATION UNDER 37 C.F.R. § 1.132

The Honorable Commissioner
Of Patents & Trademarks
Washington, D.C. 20231

Sir:

I, A.K. Gunnar Aberg, declare:

THAT I am a citizen of Sweden, a permanent resident of the USA, and resident of the City of Sarasota, Sarasota County, Florida;

THAT I am now the Chief Executive Officer of BRIDGE PHARMA, Inc., 902 Contento Street, Sarasota, Florida 34242. From 1968 to 1973, I was Director of Pharmacology at Bofors Nobel-Pharma (Sweden); from 1974 to 1978, I was Group Leader in General Pharmacology at AB Hässle (Sweden); from 1978 to 1980, I was Director of Pharmacology at Astra (USA); from 1980 to 1982, I was Director of Cardiovascular Pharmacology at Ciba-Geigy (USA); from 1982 to 1992, I was Director and Executive Director of Pharmacology at Squibb and Bristol-Myers Squibb; and from 1992 to 1996, I was Vice President and Senior Vice President of Research at Sepracor Inc.; in 1996, I founded Bridge Pharma, Inc. in Sarasota, Florida;

THAT I am a graduate of the University of Linköping, Sweden from which I hold a Ph.D. degree in Pharmacology and of the University of Gothenburg, Sweden from which I hold a degree in Zoophysiology, and that I am a docent (Associate Professor) in Applied Pharmacology at the University of Linköping, Sweden;

THAT I have over thirty years of industrial experience of pharmacological research;

THAT I am an author of over one hundred publications on pharmacological and toxicological topics, including eighteen publications and abstracts on drugs that are used in asthma;

THAT my Ph.D. thesis in pharmacology concerned pharmacological effects of optically active isomers and that forty of my publications concern biological activities of optically active isomers of various drugs;

THAT I am an inventor of approximately 50 U.S. patents and a number of pending patent applications, including the present Patent Application;

THAT I am familiar with the prosecution of the application in the present case;

THAT I prepared and executed a Declaration Under 37 C.F.R. § 1.132 that was filed in the present case as part of an Amendment on July 25, 2003, said Declaration having an execution date of June 6, 2003 (hereinafter "the 2003 Declaration");

THAT it has come to my attention that typographical errors exist in the 2003 Declaration. The errors are found in the Table on Page 15, and a corrected Table is found below, where the corrected data are underlined and shown in bold text.

| | **Oral Dose (mg/kg)** | **Sedated animals** |
|---|---|---|
| RS-KETOTIFEN | 100 | 9/10 |
| RS-KETOTIFEN | 150 | 10/10 |
| R-KETOTIFEN | 150 | 9/10 |
| S-KETOTIFEN | 150 | 3/10 |
| RS-NORKETOTIFEN | 100 | **3/10** |
| RS-NORKETOTIFEN | 150 | **3/10** |
| S-NORKETOTIFEN | 100 | 0/10 |
| S-NORKETOTIFEN | 150 | 0/10 |
| R-NORKETOTIFEN | 100 | 3/10 |
| R-NORKETOTIFEN | 150 | 3/10 |
| VEHICLE | — | 1/10 |
| VEHICLE | — | 0/10 |
| LORATADINE(*) | 150 | 1/10 |
| DIPHENHYDRAMINE (*) | 100 | 8/10 |

(*) Previous tests

The typographical errors concern the number of sedated animals caused by administration of racemic norketotifen. These data were obtained from two sedation studies performed on racemic norketotifen prior to the signing of the 2003 Declaration. Specifically, in a study performed in April, 1997 by the independent research organization Chrysalis (now called Calvert), located in Olyphant, Pennsylvania, it was found that 3 out of 10 animals became sedated and survived the test after being dosed orally either with 100 mg/kg or 150 mg/kg of racemic norketotifen. In another study performed in October, 2000, the researchers of Chrysalis repeated the studies on RS-norketotifen, and confirmed that 3 out of 10 animals became sedated and survived after being dosed orally either with 100 mg/kg or 150 mg/kg of racemic norketotifen.

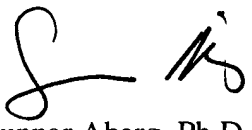
Accordingly, the sedation data reported in the 2003 Declaration for racemic norketotifen of 0/10 for the 100 mg/kg dose and 1/10 for the 150 mg/kg dose were incorrect; the correct sedation data is as shown in the Table above, and clearly demonstrates that although racemic

norketotifen has less sedative activity than racemic ketotifen, is still possesses significant sedative activity.

These corrected results are consistent with the results reported for racemic norketotifen in column 4 of U.S. Patent No. 6,207,683 (which also lists me as an inventor), where mice were administered an amount of norketotifen HCl that corresponded to 83 mg/kg of the free base of racemic norketotifen. (A dose of 83 mg/kg of the free base is equivalent to approximately 97 mg/kg of norketotifen hydrochloride salt.) The survival rate was again 3/10. A copy of U.S. Patent No. 6,207,683 is attached hereto for convenience.

I further declare that all statements of the foregoing declaration made of my own knowledge are true and that those made upon information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statement may jeopardize the validity of the above-identified application or any patent issuing thereon.

Signed by me on this 30th day of November, 2006



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